

No longer treating different conditions identically

As part of the Business and Science in Dialogue series, an information forum entitled 'Personalised Healthcare – the Custom-Made Pill?' was held at the Congress Center Basel on 16 October. Experts gave presentations and talked to laypeople about the core aspects and issues associated with a subject that will increasingly characterise, and indeed revolutionise, medicine in the future. Public awareness of the topic is now starting to rise as it is taken up by the daily press. One question that was discussed at length during the information forum was the issue of whether health insurers would only pay for medicines whose effectiveness is guaranteed by genetic testing. Today one in three medicines fails to produce the desired effect; only around two-thirds of all patients actually benefit from their drug treatment. In fact one in seven or eight patients actually feels worse after treatment than beforehand. This situation is not particularly satisfactory. It is unsatisfactory for patients or doctors, because neither the desired effects nor the side effects can be clearly defined or reliably calculated, and it is unsatisfactory for health insurers because they are having to pay for treatments whose quality leaves a lot to be desired in many cases. But neither is it satisfactory for the regulatory authorities, because they sometimes feel obliged to approve medicines that may not perhaps be clinically superior.

Quantum leap thanks to personalised healthcare

This is precisely why the concept of personalised healthcare, where treatment is tailored to the specific needs of individual patient groups, obviously makes so much sense. This new approach will therefore also increasingly be favoured by the key stakeholders in the healthcare system (doctors, health insurance funds and regulatory authorities). It could perhaps be described as a quantum leap in drug therapy. Drugs will only be used when their benefits can be clearly demonstrated in advance by biomarker tests. This would represent a significant advantage over existing medical practice, since what we know about the efficacy of treatments has, until now, been based primarily on statistics that treat the whole population identically. Jean-Jacques Garaud, Head of Global Development in Roche's Pharmaceuticals Division, summed up the situation as follows: «People are all different, but drugs are not yet differentiated enough. There is a great need for more effective and safer medicines.» Just to avoid any misunderstanding, personalised healthcare should not be (mis)interpreted as meaning that every single person receives tablets made just for them. Rather it expresses the idea



The AmpliChip-CYP455 test can identify genetic differences in the rates at which a range of important drugs are metabolised, thereby enabling doctors to 'personalise' dosages.

that groups of individuals with shared features – for example genetic characteristics – can be 'bundled together' in such a way that treatments can be optimally tailored to their needs. Strictly speaking therefore, we should really refer to it as 'less impersonal' healthcare. But the important point is that different people are no longer treated identically, but in a way that is suitable for their particular illness and needs. Standardisation is giving way to differentiation. Today's technological, molecular biological and pharmacogenetic tools and findings are increasingly helping to make personalised



Jean-Jacques Garaud, Head of Global Development in the Pharmaceuticals Division and a staunch supporter of personalised healthcare: «Much still needs to be done before we see a breakthrough in personalised healthcare. It won't be easy and it will take time. But in terms of benefits to patients and the future of the industry, it is the right, if not the only viable, route.»

— Photos: Bruno Caflisch

healthcare a reality – particularly at Roche and indeed thanks to Roche.

Roche in an enviable starting position

Any course of treatment starts with a diagnosis, i.e. identifying the patient's illness as accurately as possible. The more accurate the diagnosis, the more successful drug therapy is likely to be. Roche is in an excellent position here since it is the only healthcare company in the world to possess top-class in-house expertise in both areas. As such we are extremely well placed to provide 'custom-made treatments' that are per-

fectly suited to patients. We are also in a good position to take a major step forward in achieving the long-held ambition of providing just the right treatment for every individual. At Roche, personalised healthcare is afforded top priority, since it represents an integral part of the company's strategy of providing clinically differentiated medicines. Jonathan Knowles, Head of Group Research, never tires of pointing out «that this type of healthcare will be crucially important to the company's future success». Personalised healthcare has already made a considerable impact at Roche, and in the world of medicine in general. A whole

Personalised healthcare involves 'stratifying' patients: Groups with different genetic features will also be treated differently (different medicines or differing dosages of the same medicine, etc.)

— Photo: Vuk Latinovic

range of illuminating examples already exists at Roche. The first example is the Roche/Genentech breast cancer drug Herceptin, which has been on the market for ten years now. Volker Booten of Pricewaterhouse-Coopers once described Herceptin as the «big-bang in the universe of personalised healthcare». Breast cancer is not a 'standardised' disease that manifests itself in the same way in all women, but one with many different 'faces', each of which can be clearly identified with the aid of effective biomarker tests. HER-2-positive breast cancer is a particularly aggressive form of the disease in which the biomarker HER-2, a receptor protein, is overexpressed. In other words, if the cancer cells have more than a certain number of receptors that human epidermal growth factor can dock onto, the breast cancer is said to be HER-2-positive. Only this form of breast cancer is suitable for treatment with Herceptin. However, 'only' some 25 percent of all breast cancer patients have the HER-2-positive form.

Herceptin opens our eyes

Herceptin shows us two things. Firstly, a biomarker test that 'stratifies', i.e. differentiates, the relevant patient population is important not just for treatment purposes, but in order to obtain regulatory approval in the first place. If, in the clinical testing phase, all breast cancer patients had been treated indiscriminately with this monoclonal antibody (trastuzumab), the positive effect in statistical terms would hardly have been good enough to obtain approval. In other words, biomarkers are important for formulating and performing meaningful clinical tests. Secondly, The once widespread fear in industrial circles that stratifying, and thus reducing, the relevant patient population would severely limit the potential market (and thus sales) of these medicines, has not been confirmed in practice. Although just 25 percent of women with aggressive, metastatic breast cancer are suitable for treatment with Herceptin, the drug now generates sales in the four billion Swiss franc range. The strength of the new approach lies in the combination of biomarker test and drug: Only differentiated diagnosis results in effective patient selection and thus to effective treatment.

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